withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

§ 520.455 Clomipramine hydrochloride tablets.

(a) *Specifications.* Each tablet contains 20, 40, or 80 milligrams of clomipramine hydrochloride.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use.* For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[64 FR 1762, Jan. 12, 1999]

§ 520.462 Clorsulon drench.

(a) *Specifications.* The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use. Cattle*—(1) *Amount.* One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) *Indications for use.* For the treatment of immature and adult liver fluke (*Fasciola hepatica*) infestations in cattle.

(3) *Limitations.* Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.530 Cythioate oral liquid.

(a) *Specifications.* Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor.* See Nos. 000859 and 010042 in § 510.600 of this chapter.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount.* 15 milligrams cythioate per 10 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5614, Feb. 14, 1984]

§ 520.531 Cythioate tablets.

(a) [Reserved]

(b) *Sponsors.* See No. 000859 in § 510.600(c) of this chapter for use of 30- and 90-milligram (mg) tablets and see No. 010042 in § 510.600(c) of this chapter for use of 30-mg tablet.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount.* 30 milligrams cythioate per 20 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under

stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5615, Feb. 14, 1984, as amended at 59 FR 26942, May 25, 1994]

§ 520.534 Decoquinate.

(a) *Specifications.* The drug is a powder containing 0.8 percent decoquinate.

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Conditions of use. Calves*—(1) *Amount.* Feed 22.7 milligrams per 100 pounds of body weight (0.5 milligram per kilogram) per day.

(2) *Indications for use.* For the prevention of coccidiosis in ruminating and nonruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii.*

(3) *Limitations.* Feed in whole milk at the rate of 22.7 milligrams per 100 pounds body weight daily (0.5 milligram per kilogram) for at least 28 days.

[64 FR 10103, Mar. 2, 1999, as amended at 64 FR 30386, June 8, 1999]

§ 520.540 Dexamethasone oral dosage forms.

§ 520.540a Dexamethasone powder.

(a) *Specifications.* Dexamethasone powder is packaged in packets containing 10 milligrams of dexamethasone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) Dexamethasone powder is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug is used as supportive therapy for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered at a dosage level of 5 to 10 milligrams per animal the first day then 5 milligrams per day as required by drench or by sprinkling on a small amount of feed.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975; 41 FR 9149, Mar. 3, 1976; 52 FR 7832, Mar. 13, 1987]

§ 520.540b Dexamethasone tablets and boluses.

(a)(1) *Specifications.* Each bolus is half-scored and contains 10 milligrams of dexamethasone.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) Dexamethasone bolus is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug may be used as supportive therapy for management of inflammatory conditions such as acute arthritic lamenesses, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(ii) Administered orally, 5 to 10 milligrams for the first day, then 5 milligrams per day as required.

(iii) Do not use in viral infections during the viremic stage. With bacterial infections, appropriate antibacterial therapy should be used.

(iv) Do not use in animals with chronic nephritis and hypercorticalism (cushingoid syndrome), except for emergency therapy.

(v) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each tablet contains 0.25 milligram of dexamethasone.[1]

(2) *Sponsors.* See Nos. 000061 and 061133 in § 510.600(c) of this chapter.